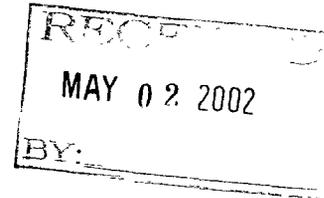


**Herbalife International of America, Inc.**  
1800 Century Park East • Century City, CA 90067-1501  
TEL 310 410 9600 x32746 • FAX 310.557.3916  
johnv@herbalife.com • www.herbalife.com

*AMJ 5/2/02*  
**John Venardos**  
Vice President  
Regulatory & Government Affairs

April 25, 2002

Office of Nutritional Products  
Labeling and Dietary Supplements  
**FOOD & DRUG ADMINISTRATION**  
200 C Street, S.W.  
Washington, D.C. 20204



80388

Ref: **K8 Tablets**

Dear Sir and/or Madam:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. has revised labeling for our K8 dietary supplement tablets. Please note the attached labels reflect revised cautionary wording as developed by industry in consultation with the agency.

K8 tablets are labeled and promoted with statements provided for in section 403(r)(6) of the Federal Food, Drug and Cosmetic Act.

**1. LABEL**

(Note: Immediately adjacent to the following copy, appears a ruled DSHEA disclaimer box.)

K8 is a combination of natural herbs, including Kava Kava and ashwagandha, as well as Calcium and is designed to help relax the body while contributing to a sense of well-being.

**2. HERBALIFE FACT SHEET**

(Note: Immediately adjacent to the following copy, appears a ruled DSHEA disclaimer box.)

Herbalife has captured the unique qualities of Kava Kava in K8. K8 contains a blend of premium-quality herbs and is designed to soothe your nerves and help you relax.\* Kava Kava is thousands of years old, yet is one of the hottest herbs on the market today. We've taken it a step further by combining it with ashwagandha, an herb known for its subtle calming properties.\* We also include the beneficial mineral Calcium.

**Discussion Points**

- **Relax and enjoy life:** K8 combines the soothing properties of Kava Kava with ashwagandha, which work together to help reduce tension levels, promote a sense of well-being and relax the body without impairing cognitive function.\*
- **A good night's sleep:** Kava Kava is now recognized by many doctors as beneficial to a good night's sleep. So if you are looking to improve your sleep pattern, turn to K8 for support without any undesirable side effects.\*
- **Enjoy a grater sense of well-being, anytime and anywhere:** This is a great product to take on business trips, vacations or wherever you go so you always have it handy when you need a "time out."

**HERBALIFE®**

975 0162 LET 9977



**An advanced kava kava dietary supplement for relaxation.**

Want to take a break from the stress of everyday life? Looking for something to smooth out life's rough edges? Interested in calming your nerves and reducing anxiety—naturally? Turn to kava kava for support. Kava, or kava kava, is a centuries-old herb that grows throughout the Polynesian islands and New Guinea. Polynesians have respected this stress-reducing plant for thousands of years and have used it for ceremonial, social and health purposes.

Herbalife has captured the unique qualities of kava kava in K8. K8 contains a blend of premium-quality herbs and is designed to soothe your nerves and help you relax.\* Kava kava is thousands of years old, yet it is one of the hottest herbs on the market today. We've taken it a step further by combining it with ashwagandha, an herb known for its subtle calming properties.\* We also include the beneficial mineral Calcium.

**Discussion Points**

- » Relax and enjoy life: K8 combines the soothing properties of kava kava with ashwagandha, which work together to help reduce tension levels, promote a sense of well-being and relax the body without impairing cognitive function.\*
- » A good night's sleep: Kava kava is now recognized by many doctors as beneficial to a good night's sleep. So if you are looking to improve your sleep pattern, turn to K8 for support without any undesirable side effects.\*
- » Enjoy a greater sense of well-being, anytime and anywhere: This is a great product to take on business trips, vacations or wherever you go so you always have it handy when you need a "time out."
- » Combine with other products: K8 can be used in conjunction with the Thermojetics® Weight-Management Programs and Herbalife's entire line of nutritional products.

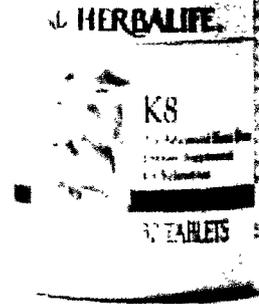
**Did You Know?**

In the early 1700s Captain Cook introduced kava kava's relaxing properties to Westerners, but it has only been in recent times that this tranquil herb has been widely accepted by industrial countries. In fact, kava kava is so popular, it has been featured in numerous health magazines, on television newsmagazines, national newspapers, and there are dozens of web sites devoted to this Polynesian herb.

Kava kava comes from the roots of the kava plant, which can grow to 15 feet tall and is identified by its large, heart-shaped leaves. The roots are harvested for usage in supplements and beverage preparations. Early usage of kava kava consisted of chewing the roots to soften them, then mixing with other fluids, usually coconut milk. This practice was largely "civilized" later on as new discoverers of the herb placed dried, crushed pieces of it in a cloth bag and squeezed the bag in coconut milk or water.

**Fast Facts**

- » A combination of natural herbs, containing kava kava and ashwagandha, an Ayurvedic herb, designed to help relax the body and promote feelings of well-being.\*
- † Each serving contains 150mg of calcium to help build strong bones.\*
- » Includes Bio-Absorption Complex-5, which helps the body absorb the beneficial properties of the herbs.\*



**SUPPLEMENT FACTS**

Serving Size: 1 tablet  
Servings per container: 30 tablets

	Amount Per Serving	% Daily Value*
Total Carbohydrate	1 g	<1%
Calcium (as dicalcium phosphate)	180 mg	18%
Dried Kava Kava Extract (30% kavalactones) (root)	200 mg	†
Dried Ashwagandha Extract (1.5% withanolides) (root)	50 mg	†
Bio-absorption Complex-5 (Lecithin, Vitamin C (as ascorbyl palmitate), Plant Cellulose Enzyme, Cinnamon Powder (bark) and Dried Black Pepper Extract (from Bioperne®) (NLT 95% piperine) (fruit))	23 mg	†

\* Percent Daily Values are based on a 2,000 calorie diet.  
† Daily Value not established.  
Other Ingredients: Microcrystalline Cellulose, Silicon Dioxide, Stearic Acid, Croscarmellose Sodium, Magnesium Stearate, Dextrin, Dextrose, Sodium Carboxymethylcellulose and Sodium Citrate

\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Suggested Serving: Take one tablet up to three times a day as needed.  
NOTICE: For adult use only. If you are under medical supervision, pregnant or nursing, consult with your physician before taking this product. Product can cause drowsiness. Discontinue use if drowsiness occurs. Do not drive a vehicle or operate machinery while using this product. Do not take concurrently with prescription anti-anxiety medicine.

**Ordering Details**  
#3051 \$13.95